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Design Specification

Nav3i Platform Family
SPC 3.1 Operating System V2

Document Control

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Change Records

Rev. No.	Comment	Date	Author
A	Initial Version	2014-09-02	Schöbel
B	Adapted	2015-02-03	Eisenhauer
	[TR1020] : option no longer available		
	[TR1030] : Wording		
	[TR1080] : removed no longer needed options, added Documents, Internet Explorer, Desktop, replaced administrative users by user NavigationAdmin		
	[TR1090] : Apps/features to be removed shall be displayed instead of installed apps, adapted list		
	[TR1300] : correct Windows name		
	[TR1470] : removed no longer available options		
	[TR1560] : Sound volume set to 100%		
	[TR1570] : inserted Realtek line out		
	[TR2050] : replaced with more restrictive CyberSecurity Setting		
	[TR2210] : added Elotec RFID device		
	[TR2250] : added note for driver version		
	[TR2350] : adapted to new Microscope script path		
	[TR2360] : added ext. mode		
	[TR2370] : added ext. mode		
	[TR2410] : option no longer available		
	[TR2480] : option no longer available		
	[TR2530] : adapted for UPS Manager setting		
	[TR3210] : added open Firewall ports		
	[TR3480] : options for NavSystem III		
	[TR3210] : removed Proximity sharing from firewall open ports		
	[TR1460] : power button option for login screen		
	[TR1620] : added reference to SADD		
	Removed		
	TR2030: Nothing to be adapted in OS for this Req.		
	TR3490: doubles TR3420		
	TR3470: doubles TR3480 and TR3490		
	TR1060: doubles TR1840		
	Content of chapter 2.1 and 2.2 with reference to [SADD]		
	Added		
	[TR3490] : options for Nav3i		
	[TR1755] : password setting for user NavigationService		
	[TR1465] : power button option when logged in		
	Replaced reference DI with DI_NAVIII and DI_NAV3I		
	Added reference RARC		
	Added traceabilty links to DI and RARC		

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Rev. No.	Comment	Date	Author
C	Used family name "Nav3i Platform Family" SPCIIIA-15: DR6: Update Design Specification OS references in "satisfies" column for DF Milestone • TR1150: Satisfies set to "None" • TR2160, TR2210: Added [DI_NAVIII.SR42050] • TR2330: Set to "None" • TR3300: Added [DI_NAVIII.SR53020] • TR2350 updated • TR2620: deleted link to DI_NAVIII • Update 3.2.13 • All requirements: Updated for Nav3Suite	2015-06-16	Schöbel
C	[TR3400] : Change acceptance criterion from "The OS shall be installable from bootable USB device or DVD drive" to "The OS shall be installable from bootable USB device" [TR2340] : Global Preset for graphics driver added [TR1950] : deleted "NavigationGroup" [TR1100] : added acceptance critrion for the case that a third party system is attached [TR2310] : changed minimum OpenGL support to 4.4 [TR3210] : added firewall rules for "Open Text..." and "Proximity Sharing" TR2160 deleted (because WLAN is deactivated during production and does not depend on the OS) TR1320 removed (setting not longer needed, because page file size managed automatically)	2015-08-13	J. Schambach
C	[TR2510] : minimum battery runtime changed from 5 to 6 minutes [TR2540] : added, auto shutdown requirement	2015-08-19	J. Schambach
D	Removed following Requirements (not needed because they are standard Windows 8.1 features): TR3520 complete TR3530 complete in TR3550: - Possibility to use MS Active Directory for centralized user authentication - System recovery feature with system restore points - Possibility of keeping file history - Possibilities to Backup/Restore system configuration and data	2015-11-18	R. Eisenhauer

Table of Contents

1   Introduction

1.1   Purpose

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The purpose of this document is to specify the properties and requirements of component Nav3i Platform Family SPC 3.1 Operating System V2.

The intended audience of this document is development, regulatory affairs and quality assurance.

1.2   Scope

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The Nav3i Platform Family SPC 3.1 Operating System V2 is a collection of software packages forming an Operating System for the Nav3i Platform Family PC.

It is designed to:

• support the specified Nav3i Platform Family hardware configurations, refer to [SADD].

• support current and future Stryker Navigation Software packages, refer to [DI_NAVIII] [DI_NAV3I] and

50   [DI_SUITE].

The requirements of the Operating System are driven by the Navigation Software packages and the computer hardware.

This document covers the requirements of the Nav3i Platform Family SPC 3.1 Operating System V2.

1.3   Definitions, Acronyms and Abbreviations

Term	Definition
DOT	Design Output Trace Reference
ESS	Essential Performance Requirement

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1.4   References

ID	Title	Rev.*	Doc. No.
SADD	SADD - NAV3i Platform Family - NAV3i Operating System (#0000012124,SPC3.1)	Auto	0000039008
TD	DMR_Technical Documentation (#0000012124,SPC3.1)	Auto	0000037758
DI_NAVIII	DI - NAV3i Platform Family - ADAPT / NAV3 (#0000010743,NavSystem III)	Auto	0000006309
DI_NAV3I	DI - NAV3i Platform Family - NAV3i (#0000011363,NAV3i)	Auto	0000014207
DI_SUITE	DI - NAV3i Platform Family - NavSuite3 (#0000012123,NavSuite3)	Auto	0000039104
RARC_NAV3I	RARC - Navigation System III - NAV3i (#0000011363,NAV3i)	Auto	0000014215
RARC_SUITE	RARC - NAV3i Platform Family - NAVSuite3 (#0000012123,NavSuite3)	Auto	0000039402
RARC_NAV3	RARC - NAV3i Platform Family - ADAPT / NAV3 (#0000010743,NavSystem III)	Auto	0000011995
STD_NAV3I	List of Applied Standards - NAV3i (#0000011363,NAV3i)	Auto	0000014416

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ID	Title	Rev.*	Doc. No.
STD_NAV3	List of Applied Standards - NavSystem III (#0000010743,NavSystem III)	Auto	0000005504
STD_SUITE	List of Applied Standards - NavSuite3 - NavSuite3 (#0000012123,NavSuite3)	Auto	0000040904
CT_OS_APP	SPC 3.1 - CT_OS_Applications (#0000012124,SPC3.1)	Auto	0000042016
CT_OS_BASE	SPC 3.1 - CT_OS_Base (#0000012124,SPC3.1)	Auto	0000041920
CT_OS_DRIV	SPC 3.1 - CT_OS_Driver (#0000012124,SPC3.1)	Auto	0000041928
CT_OS_INST	SPC 3.1 - CT_OS_Installability_Reliability (#0000012124,SPC3.1)	Auto	0000042043
CT_OS_NET	SPC 3.1 - CT_OS_Network_User (#0000012124,SPC3.1)	Auto	0000042032

*Auto: Document's revision number is updated automatically by OfficeTrace.

2 Sub-System/Component Context

2.1 Architectural Overview

For information about the software architecture please refer to [SADD].

2.2 Operating System V2 components and interfaces

For information on the software components please refer to [SADD].

2.3 Interfaces

For a description of all interfaces please refer to [SADD]

2.4 User Interfaces

The user Navigation interacts with the system by using the Login Screen and the Application Manager.

The administrative user NavigationAdmin interacts with the system by using the Login Screen, the Application Manager and the MS Windows interfaces.

Both users Navigation and NavigationAdmin interact with the system using the IO Tablet.

User interface requirements are specified in section 3.1 User Interface Requirements

2.5 List of Applied Standards

All standards which are applied to the development process or product itself are listed in [STD_NAV3I], [STD_NAV3], [STD_SUITE].

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3 Detailed Requirements

3.1   User Interface Requirements

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR1000	No interruption during normal operation – screen saver	Screen Saver shall be deactivated	Y	None	[CT_OS_BASE]
TR1010	No interruption during normal operation – action center	Action Center alert shall be deactivated	Y	None	[CT_OS_BASE]
TR1020	No interruption during normal operation – error reporting	Error reporting to Microsoft shall be disabled .	Y	None	[CT_OS_BASE]
TR1030	No interruption during normal operation – task bar	Task bar must not overlap navigation applications. • Enable auto hide • Disable keep the taskbar on the top of other windows. • All shortcuts removed from the quick launch • All notification balloon tips are disabled	Y	None	[CT_OS_BASE]
TR1040	No interruption during normal operation – standby mode	System must not switch in any standby mode (power options). • Power schemes: Always On • Turn off monitor: Never Turn off hard disks: Never	Y	None	[CT_OS_BASE]
TR1050	No interruption during normal operation – automatic logoff	Automatic logoff or screen lock shall be deactivated	Y	None	[CT_OS_BASE]
TR1070	Straightforward OS user interface – NavigationAdmin	Only the following shortcuts shall be initially shown on desktop of the user NavigationAdmin: • My Computer • My Network Places • Recycle Bin • Internet Explorer	N	None	[CT_OS_BASE]
TR1080	Straightforward OS user interface – Start Menu	Start Menu for user NavigationAdmin shall contain only: • Help & Support • Search	N	None	[CT_OS_BASE]

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		• Documents • Internet Explorer • Desktop			
TR1090	Unnecessary apps shall be removed	The following apps shall be deactivated: • Windows Store • „add features to Windows 8.1" wizard • OneDrive	N	None	[CT_OS_BASE]
TR1100	Windows Bootup Feedback Time	During bootup there shall not be a black screen for longer than 10 seconds. If a third party system is attached, black screen can be shown for 30sec.	N	None	[CT_OS_BASE]
TR1110	Windows Start Screen – Navigation user	Windows shall directly boot to Applications Manager after login. There shall be no start screen, task bar or desktop for user Navigation.	N	None	[CT_OS_BASE]
TR1120	Windows Start Screen- NavigationAdmin user	Windows shall directly boot to Application Manager after login, start screen shall be deactivated, the task bar and start button shall be visible for user NavigationAdmin.	N	None	[CT_OS_BASE]

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3.2   Software Components Requirements

3.2.1 SW1, Application Manager

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR1150	Installation of Application Manager	Application Manager shall be installed.	N	None	[CT_OS_APP]

85 ### 3.2.2   SW2, SFB Driver

Note: This chapter is only relevant for Stryker Navigation systems with SFB Camera.

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means

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TR1200	SFB driver installation	SFB driver shall be installed *Note:* for SFB driver version refer to [SADD].	Y	[DI_NAVIII.SR43010] [DI_NAV3I.SR43010] [DI_SUITE.SR404010]	[CT_OS_DRIV]
TR1210	SFB driver availability	The FP6000 Camera shall be visible in the Device Manager without errors or warnings	Y	[DI_NAVIII.SR43010] [DI_NAV3I.SR43010] [DI_SUITE.SR404010]	[CT_OS_DRIV]
TR1220	It shall be possible to send and receive data from the FP6000 Camera via the Fire Wire connection.	It is possible to connect a tracker in the Navigated Instrument Checker	Y	[DI_NAVIII.SR43010] [DI_NAV3I.SR43010] [DI_SUITE.SR404010]	[CT_OS_DRIV]

3.2.3 SW3, Windows OS base

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR1300	Operating System Version	Microsoft Windows® embedded 8.1 industry pro x64	N	None	[CT_OS_BASE]
TR1310	Test Mode	Windows shall not run in test mode.	N	None	[CT_OS_BASE]
TR1330	Hard Disk Partitions – system	System shall have a separate System hard disk partition No Drive label $\geq$ 320 MB	N	None	[CT_OS_BASE]
TR1340	Hard Disk Partitions – Windows	System shall have a separate Windows hard disk partition Drive label C: $\geq$ 80 GB	N	None	[CT_OS_BASE]
TR1350	Hard Disk Partitions - Data	System shall have a separate Data hard disk partition Drive label D: $\geq$ 120 GB	N	None	[CT_OS_BASE]
TR1360	Hard Disk Partitions - Backup	System shall have a separate Backup hard disk partition Drive label Z: $\geq$ 80 GB	N	None	[CT_OS_BASE]
TR1370	Hard Disk Encryption	It shall be possible for administrative users to encrypt partitions of the Hard Disk, please refer to [TD]	N	None	[CT_OS_BASE]
TR1380	Optical Drive Letter	System shall assign "E" drive letter to optical drive.	N	None	[CT_OS_BASE]
TR1390	Computer Name	System shall use "STRYKER-IGS" as computer Name	N	None	[CT_OS_BASE]
TR1400	Time Zone	Central Time (US & Canada) time zone shall be used.	N	None	[CT_OS_BASE]
TR1410	Regional options – location	Location shall be set to United States	N	[DI_NAVIII.SR56010]	[CT_OS_BASE]

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				[DI_NAV3I.SR56010] [DI_SUITE.SR506010]	
TR1420	Regional options – Date	Supported Date Format: MM/DD/YYYY	N	[DI_NAVIII.SR56010] [DI_NAV3I.SR56010] [DI_SUITE.SR506010]	[CT_OS_BASE]
TR1430	Regional options – language	Supported language: English, (United States)	N	[DI_NAVIII.SR56010] [DI_NAV3I.SR56010] [DI_SUITE.SR506010]	[CT_OS_BASE]
TR1440	Regional options – decimal symbol	Dot(.) shall be used for decimal symbol.	N	[DI_NAVIII.SR56010] [DI_NAV3I.SR56010] [DI_SUITE.SR506010]	[CT_OS_BASE]
TR1450	System Clock Update	Automatic clock update from internet time servers shall be disabled.	N	None	[CT_OS_BASE]
TR1460	Shutdown Option – Login screen	In the Login Screen the IO-Tablet power button shall shutdown the system immediately. Note: power button controlled by c:\programs\application_manager\bin\shutdown_manager	N	None	[CT_OS_BASE]
TR1465	Shutdown Option –Logged in	When the user is logged in the IO-Tablet power button shall offer a user dialog with the options Shutdown, Logoff and Cancel	N	None	[CT_OS_BASE]
TR1470	Disabled services	Following services shall be disabled. • Computer Browser • Distributed Link Tracking Client	N	None	[CT_OS_BASE]
TR1480	Original equipment manufacturer (OEM) info - Logo	Stryker-Logo shall be visible in OEM (original Equipment Manufacturer) info shown in system properties.	N	None	[CT_OS_BASE]
TR1490	Original equipment manufacturer (OEM) info - support	Support information shall be displayed in System Properties	N	None	[CT_OS_BASE]
TR1500	Version Control	The text file c:\ghostversion.txt shall identify the version of the Navigation System III operating system	N	None	[CT_OS_BASE]
TR1510	Desktop Background – Navigation user	desktop background shall be blank for user Navigation	N	None	[CT_OS_BASE]

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TR1520	Support of Direct X	Direct X shall be installed *Note*: for Direct X version refer to [SADD]	N	None	[CT_OS_BASE]
TR1530	Support of IO Tablet	The following IO Tablet functions shall work: • DVD drive • RFID Reader • IO Tablet buttons • Watchdog indicator LEDs • Touch screen • Onscreen keyboard • USB port for Mouse • Full HD Screen • USB ports	Y	[DI_NAVIII.SR44010] [DI_NAVIII.SR44070] [DI_NAVIII.SR46010] [DI_NAVIII.SR46030] [DI_NAVIII.SR46040] [DI_NAV3I.SR44010] [DI_NAV3I.SR44040] [DI_NAV3I.SR44060] [DI_NAV3I.SR44070] [DI_NAV3I.SR46010] [DI_NAV3I.SR46030] [DI_NAV3I.SR46040] [DI_SUITE.SR401010] [DI_SUITE.SR401040] [DI_SUITE.SR401060] [DI_SUITE.SR401070][DI_SUITE.SR405010] [DI_SUITE.SR405010] [DI_SUITE.SR405020]	[CT_OS_BASE]
TR1540	LiveCam – device	The LiveCam shall be visible without errors or warnings in the Device Manager	N	None	[CT_OS_BASE]
TR1550	LiveCam – micro	LiveCam has integrated microphone. Microphone Sound is available on system.	N	[DI_NAV3I.SR410050]	[CT_OS_BASE]
TR1560	Sound I/O - volume	Sound volume can be adjusted from 0% to 100%. Standard volume is set to 100%	N	None	[CT_OS_BASE]
TR1570	Sound I/O - output	Standard sound output is set to Realtek line out and sound is audible through this port.	N	None	[CT_OS_BASE]
TR1580	Printer	Microsoft XPS document writer is installed as default printer. No other printer device available.	N	None	[CT_OS_BASE]
TR1590	Boot Time – start	Login Screen shall be available within 4 minutes after system start	Y	None	[CT_OS_BASE]
TR1600	Boot Time – restart	Login Screen shall be available within 4 minutes after System restart	Y	None	[CT_OS_BASE]

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TR1610	Automatic update disabled – windows	Automatic updates shall be disabled for Windows	Y	[RARC_NAV3I.RC82] [RARC_SUITE.RC82] [RARC_NAV3.RC82]	[CT_OS_BASE]
TR1620	Automatic update disabled – 3rd party	Automatic updates shall be disabled for installed 3rd party software, for a list of 3rd party software refer to [SADD]	Y	[RARC_NAV3I.RC82] [RARC_SUITE.RC82] [RARC_NAV3.RC82]	[CT_OS_BASE]
TR1630	Operating System – MBSA	Microsoft Baseline Security Analyzer must not detect any critical findings, except weak passwords	Y	None	[CT_OS_BASE]
TR1640	Operating System - updates	Critical security updates which were available when the OS installation medium was built shall be installed.	Y	None	[CT_OS_BASE]

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3.2.3.1 User Management

3.2.3.1.1 Active users

- Navigation: used for surgery personnel
- NavigationAdmin: used for application administration tasks, normally the Stryker Sales Representative
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- NavigationService: used for system administration tasks, normally the IT personnel of the hospital

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR1700	Different user support - NavigationAdmin	System shall have an administrative user called NavigationAdmin.	N	None	[CT_OS_NET]
TR1710	Different user support – NavigationAdmin enabled	The NavigationAdmin user shall be enabled	N	None	[CT_OS_NET]
TR1720	Different user support - Navigation	System shall have a non-administrative user for Surgery called Navigation	N	None	[CT_OS_NET]
TR1730	Different user support – Navigation enabled	The Navigation user shall be enabled	N	None	[CT_OS_NET]
TR1740	Different user support - NavigationService	System shall have an administrative user called NavigationService	N	None	[CT_OS_NET]
TR1750	Different user support – NavigationService disabled	The NavigationService user shall be disabled	N	None	[CT_OS_NET]

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ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR1755	Different user support – NavigationService password	User NavigationService must change password at first login.	N	None	[CT_OS_NET]
TR1760	Different user support – password expiration	Passwords for users must not expire Only exception is user NavigationService, see [TR1755]	N	None	[CT_OS_NET]
TR1770	Different user support – password change	users shall be able to change the password	N	None	[CT_OS_NET]
TR1780	User Groups	NavigationGroup shall contain • Navigation (User) • NavigationAdmin (User) • NavigationService (User) • Administrator (User)	N	None	[CT_OS_NET]
TR1790	Different user support – login attempts	Users are not locked out after a specified number of login attempts without success	N	None	[CT_OS_NET]
TR1800	The system provides password protection at login.	A user / password identification mask in order to login to the system shall be provided	Y	[DI_NAVIII.SR513010] [DI_NAV3I.SR513010] [DI_SUITE.SR513010]	[CT_OS_NET]
TR1810	User logon logging	Each user login shall be logged	N	None	[CT_OS_NET]
TR1820	Access rights	File and directory read / write protection on operating system level shall be possible	N	None	[CT_OS_NET]
TR1830	Access rights for non-administrative users	No administrator rights for members of group "Users"	N	None	[CT_OS_NET]
TR1840	User account lock	Every user can use the manual keyboard shortcut Windows-L to lock his user account	N	None	[CT_OS_NET]

3.2.3.1.2   Legacy application users

For the installation of the legacy applications Fluoro, Hip, UniKnee, ASMKnee, CTHIP1, HipRsurf and Knee4 the following users must be available on the operating system for every application: <ApplicationName>, <ApplicationNameAdmin>, <ApplicationNameService> and the appropriate user groups. These users and user groups are needed for the installation of the appropriate application package only. All these users are disabled.

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ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR1900	Legacy application Users – users	System shall have following application users for the legacy Navigation Applications • <ApplicationName> • <ApplicationName>Admin • <ApplicationName>Service	N	None	[CT_OS_NET]

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TR1910	Legacy application Users – profile	All the users shall have their profile created.	N	None	[CT_OS_NET]
TR1920	Legacy application Users – password	All the application users at same level shall have same login password. For e.g Hip, AsmKnee shall have same password. HipAdmin , AsmKneeAdmin shall have same password. HipService , AsmKneeService shall have same password.	N	None	[CT_OS_NET]
TR1930	Legacy application Users - disabled	All legacy application user accounts shall be disabled.	N	None	[CT_OS_NET]
TR1940	Legacy application User Groups – application groups	Following user groups shall be created: FluoroGroup, HipGroup, NavigationGroup, UniKneeGroup, ASMKneeGroup, CTHIP1Group, HipRsurfGroup , Knee4Group	N	None	[CT_OS_NET]
TR1950	Legacy application User Groups - members	Respective package users in the groups. For e.g. HipGroup shall contain: • Hip (User) • HipAdmin (User) • HipService (User)	N	None	[CT_OS_NET]

3.2.3.2 Internet Explorer

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR2000	Support of Internet Explorer	Internet Explorer shall be installed	N	None	[CT_OS_APP]
TR2010	Internet Explorer - interface	The internet explorer shall be setup that the user Navigation can open local html files	N	None	[CT_OS_APP]
TR2020	Internet Explorer - browser look non-admin	Toolbars and status bar shall not be displayed for user Navigation	N	None	[CT_OS_APP]
TR2040	Internet Explorer Settings –sites	Trusted sites and restricted sites shall be empty	N	None	[CT_OS_APP]
TR2050	Internet Explorer Settings – security level	All security levels shall be set to High	N	None	[CT_OS_APP]

105 ### 3.2.3.3 Network configuration

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means

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TR2100	Local Area Connection – Ethernet	Ethernet Network adapter shall be installed	Y	[DI_NAVIII.SR42040] [DI_NAV3I.SR42030] [DI_SUITE.SR402030]	[CT_OS_NET]
TR2110	Local Area Connection – MS network client	Client for Microsoft Networks protocol shall be enabled.	N	None	[CT_OS_NET]
TR2120	Local Area Connection – sharing	File and Printer Sharing for Microsoft Networks protocol shall be enabled.	N	None	[CT_OS_NET]
TR2130	Local Area Connection – tcp	Internet Protocol (TCP/IP) protocol shall be enabled.	N	None	[CT_OS_NET]
TR2140	Local Area Connection – WLAN	Wireless LAN (WLAN) adapter shall be installed.	N	[DI_NAVIII.SR42050] [DI_NAV3I.SR42040] [DI_SUITE.SR402040]	[CT_OS_NET]
TR2150	Local Area Connection – WLAN activation	It shall be possible to enable/disable WLAN	N	None	[CT_OS_NET]
TR2170	Local Area Connection – DHCP	All LAN and WLAN connections shall get IP and DNS automatically	N	None	[CT_OS_NET]
TR2180	Local Area Connection – systray	LAN and WLAN Icons shall be visible in system tray	N	None	[CT_OS_NET]

3.2.4 SW4, RFID Driver

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR2200	RFID Reader Driver availability	RFID Reader driver is installed and the RFID Reader is visible in the Device manager without errors and warnings.	N	[DI_NAVIII.SR44100] [DI_SUITE.SR401070]	[CT_OS_DRIV]
TR2210	RFID driver compatibility	RFID driver for both RFID devices ASK 407 and Elotec shall be available	N	[DI_NAVIII.SR44100] [DI_SUITE.SR401070]	[CT_OS_DRIV]

3.2.5 SW5, Frame Grabber Driver

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means

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TR2250	Frame grabber Driver – installation	Frame grabber driver is installed and the frame grabber is visible in the Device manager without errors and warnings. Note: for Framegrabber driver version refer to [SADD].	Y	[DI_NAVIII.SR42060] [DI_NAV3I.SR42050] [DI_SUITE.SR402050]	[CT_OS_DRIV]
TR2260	Frame grabber Driver – BNC PAL	Live PAL video from BNC connector shall be displayed in Application Manager\Service tools\Video Adjustment.	Y	[DI_NAVIII.SR42060] [DI_NAV3I.SR42050] [DI_SUITE.SR402050]	[CT_OS_DRIV]
TR2270	Frame grabber Driver – S-Video PAL	Live PAL video from S-Video connector shall be displayed in Application Manager\Service tools\Video Adjustment.	Y	[DI_NAVIII.SR42060] [DI_NAV3I.SR42050] [DI_SUITE.SR402050]	[CT_OS_DRIV]
TR2280	Frame grabber Driver – BNC NTSC	Live NTSC video from BNC connector shall be displayed in Application Manager\Service tools\Video Adjustment.	Y	[DI_NAVIII.SR42060] [DI_NAV3I.SR42050] [DI_SUITE.SR402050]	[CT_OS_DRIV]
TR2290	Frame grabber Driver – S-Video NTSC	Live NTSC video from S-Video connector shall be displayed in Application Manager\Service tools\Video Adjustment.	Y	[DI_NAVIII.SR42060] [DI_NAV3I.SR42050] [DI_SUITE.SR402050]	[CT_OS_DRIV]

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3.2.6 SW6, Graphics Driver

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR2300	Graphics Card Driver availability	Graphics card driver is installed and the graphics card is visible in the Device manager without errors and warnings.	Y	None	[CT_OS_DRIV]
TR2310	Render Engine support	Graphics driver shall support the features of at least OpenGL 4.4	N	None	[CT_OS_DRIV]
TR2320	Screen Settings – Full HD	Screen shall correctly display navigation application CranialMap with native resolution 1920x1080 without scaling in clone mode.	Y	[DI_NAVIII.SR512010] [DI_NAV3I.SR512010] [DI_SUITE.SR403030]	[CT_OS_DRIV]
TR2330	Screen Settings - 1280	Screen shall correctly display navigation application CTHip with native resolution 1280x1024 without scaling in clone mode.	N	None	[CT_OS_DRIV]
TR2340	Global Preset	Global Preset for graphics driver shall be set to "Workstation App - Dynamic Streaming"	N	None	[CT_OS_DRIV]

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3.2.7 SW7, Microscope Kit

115   Note: This chapter is only relevant for Stryker Navigation Systems used with a microscope. Image injection display shall be supported on the microscope Video output. Resolution and clock rate can be set independently from Primary Video settings.

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR2350	Script – microscope init	Copy scripts for microscope initialization to c:\install\display\microscope	Y	[DI_NAV3I.SR49010] [DI_NAV3I.SR49020] [DI_NAV3I.SR49030] [DI_SUITE.SR407010] [DI_SUITE.SR407020] [DI_SUITE.SR407030]	[CT_OS_DRIV]
TR2360	Script - LEICA	• Switch from clone mode to extended mode • Attach microscope image injection display • Set resolution of microscope image injection display to 1024x768, 60 Hz	Y	[DI_NAV3I.SR49030] [DI_SUITE.SR407030]	[CT_OS_DRIV]
TR2370	Script - ZEISS	• Switch from clone mode to extended mode • Attach microscope image injection display • Set resolution of microscope image injection display to 800x600, 60 Hz	Y	[DI_NAV3I.SR49020] [DI_NAV3I.SR49010] [DI_SUITE.SR407020] [DI_SUITE.SR407010]	[CT_OS_DRIV]

3.2.8 SW8, PDF Reader

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR2400	Support of Acrobat Reader	Acrobat Reader version $\geq$ 11.0 shall be installed.	N	None	[CT_OS_APP]
TR2410	Adobe Acrobat configuration	Adobe acrobat shall be configured as follows: • Online updates shall be configured manually. All Web browser Options shall be off	N	None	[CT_OS_APP]

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120   ### 3.2.9 SW9, Virus Scanner

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR2450	Virus Scanner – product	Microsoft Defender is installed and activated.	Y	[RARC_NAV3I.RC81] [RARC_SUITE.RC81] [RARC_NAV3.RC81]	[CT_OS_APP]
TR2460	Virus Scanner – update	Virus scanner updates shall be installed automatically after login when internet connection is available.	Y	None	[CT_OS_APP]
TR2470	Virus Scanner – setting	Virus scan 'On Access' shall be enabled for all drives except the DVD drive.	Y	None	[CT_OS_APP]
TR2480	Virus Scanner – schedule	Virus scanner must not interrupt navigation	Y	None	[CT_OS_APP]

3.2.10 SW10, UPS Service

Note: This chapter is only relevant for Stryker Navigation Systems with UPS (Uninterruptable Power Supply).

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR2500	UPS – availability	The UPS driver, service and Tools shall be installed and the UPS shall be visible in the system tray.	N	None	[CT_OS_DRIV]
TR2510	UPS – settings	It shall be possible to disconnect the system from main power for at least 6 minutes without a restart and additional set up steps.	N	[DI_NAV3I.SR47010]	[CT_OS_DRIV]
TR2520	UPS – disconnect	System displays MessageBox in foreground during UPS mains disconnection	N	None	[CT_OS_DRIV]
TR2530	UPS – battery	UPS Manager shall be configured that system displays MessageBox in foreground in the case the battery down time is lower than 10 minutes	N	None	[CT_OS_DRIV]
TR2540	UPS – system shutdown	The Navigation System shall shut down automatically if the remaining on-battery runtime is lower than 10 minutes.	N	None	[CT_OS_DRIV]

125   ### 3.2.11 SW11, CanUSB Driver

Note: This chapter is only relevant for Stryker Navigation Systems when a microscope kit is installed and configured for LEICA microscopes.

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ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR2550	CanUSB availability	The CanUSB driver shall be installed and the CanUSB device shall be visible in the Device Manager without errors or warnings.	N	None	[CT_OS_DRIV]
TR2560	Support of surgical microscopes	CAN interface available to connect the supported Leica microscope interface.	Y	[DI_NAV3I.SR512010] [DI_NAV3I.SR49030] [DI_SUITE.SR407030]	[CT_OS_DRIV]

3.2.12 SW12, EdgePort Driver

Note: This chapter is only relevant for Stryker Navigation Systems when a microscope kit is installed and configured for ZEISS microscopes.

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR2600	EdgePort availability	The Edgeport driver shall be installed and the Edgeport device shall be visible in the Device Manager without errors or warnings.	N	None	[CT_OS_DRIV]
TR2610	Support of surgical microscopes – RS232	Additional 2 standard serial RS232 ports available to connect to Zeiss microscope interface via USB-RS232 Adapter.	Y	[DI_NAV3I.SR512010] [DI_NAV3I.SR49010] [DI_NAV3I.SR49020] [DI_SUITE.SR407010] [DI_SUITE.SR407020]	[CT_OS_DRIV]
TR2620	Support of surgical microscopes – COM ports	Data can be sent and received on COM3 and COM4.	Y	[DI_NAV3I.SR512010] [DI_NAV3I.SR49010] [DI_NAV3I.SR49020] [DI_SUITE.SR407010] [DI_SUITE.SR407020]	[CT_OS_DRIV]

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3.2.13 SW13, AXEDA Services

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR2700	Axeda Agent - Installation	The Agent service shall be installed.	N	[DI_NAV3I.SR514110] [DI_SUITE.SR514110]	[CT_OS_NET]

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TR2710	Axeda Agent - default	The Agent service shall be disabled by default	N	None	[CT_OS_NET]
TR2720	Axeda Agent – serial number	The Navigation System's serial number and model shall be configurable in the Axeda Agent.	N	None	[CT_OS_NET]
TR2730	Axeda Agent – stryker axeda server	The address of the Stryker Axeda Server shall be configurable in the Axeda Agent.	N	None	[CT_OS_NET]
TR2740	Axeda Agent – secure connection	The connection between Agent and Server shall be secured by certificate .	N	None	[CT_OS_NET]
TR2750	Axeda Agent – frequency	The Axeda Agent shall connect to the server every 10 seconds in order to process any pending requests.	N	None	[CT_OS_NET]
TR2760	Axeda Agent – push files	It shall be possible to push files from the Stryker Axeda Server to the Navigation System.	N	[DI_NAV3I.SR514130] [DI_NAV3I.SR514140] [DI_SUITE.SR514130] [DI_SUITE.SR514140]	[CT_OS_NET]
TR2770	Axeda Agent – interface	It shall be possible to access the Stryker Axeda Server from the Navigation System's Internet Explorer.	N	None	[CT_OS_NET]
TR2780	Axeda Agent – HDD space	The Agent shall send the available hard disk space on partition D: to the Stryker Axeda Server every 60 minutes.	N	[DI_NAV3I.SR514170] [DI_SUITE.SR514170]	[CT_OS_NET]
TR2790	Axeda Agent – free HDD underrun	The Stryker Axeda Server shall display an alarm if the free hard disk space decreases under 50%.	N	None	[CT_OS_NET]
TR2800	Axeda Agent – crash alert	The Agent shall send information to the Stryker Axeda Server in case a system crash occurred. These information shall trigger the Stryker Axeda Server to display an alarm signal.	N	None	[CT_OS_NET]
TR2810	Axeda Desktop Server – remote session	Axeda Desktop Server shall be installed. The Stryker Axeda Server shall be able to open a remote session on the Navigation System.	N	[DI_NAV3I.SR514110] [DI_NAV3I.SR514150] [DI_SUITE.SR514110] [DI_SUITE.SR514150]	[CT_OS_NET]
TR2820	Axeda Desktop Server – remote password	Remote access shall be password protected. Remote access shall only be possible if the remote user provides the correct password.	N	[DI_NAV3I.SR514125] [DI_SUITE.SR514125]	[CT_OS_NET]
TR2830	Axeda Desktop Server – password change	It shall be possible to change the password on the Navigation System.	N	None	[CT_OS_NET]
TR2840	Axeda Desktop Server – remote	If a user is logged in on the Navigation System, he must accept the remote session if he agrees with the access. If he doesn't accept	N	[DI_NAV3I.SR514120]	[CT_OS_NET]

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	agree	within 30 seconds, remote access shall be rejected automatically.		[DI_SUITE.SR514120]	
TR2850	Axeda Desktop Server – local acceptance	If no user is logged in, no local acceptance shall be necessary	N	[DI_NAV3I.SR514190] [DI_SUITE.SR514190]	[CT_OS_NET]
TR2860	Axeda Desktop Server – Navigationadmin access	If the NavigationAdmin user is logged in, it shall be possible to access mouse and keyboard remotely.	N	[DI_NAV3I.SR514150] [DI_SUITE.SR514150]	[CT_OS_NET]
TR2870	Axeda Desktop Server – Navigation access	If a normal Navigation user is logged in, mouse and keyboard shall not be accessible remotely.	N	[DI_NAV3I.SR514160] [DI_SUITE.SR514160]	[CT_OS_NET]
TR2880	Axeda Desktop Server – file transfer	It shall be possible to transfer files from and to the remote system.	N	[DI_NAV3I.SR514155] [DI_SUITE.SR514155]	[CT_OS_NET]
TR2890	Axeda Desktop Server - default	The Axeda Desktop Server service shall be disabled by default	N	None	[CT_OS_NET]

3.2.14 SW14, X Server 3D

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR3000	Support of Exceed software	Exceed and Exceed 3D shall be installed *Note:* For Exceed version refer to [SADD]	N	None	[CT_OS_APP]
TR3010	Executable encryption	The corresponding exceed.exe file shall be packed in a password protected (=encrypted) archive The original exceed.exe file shall be deleted.	N	None	[CT_OS_APP]
TR3020	Exceed Settings – screen	All applications start up with one screen	N	None	[CT_OS_APP]
TR3030	Exceed Settings – 112 dpi	Parameter "compute based on monitor" set to 112 dots per inch	N	None	[CT_OS_APP]
TR3040	Exceed Settings .- stpfont	Font defaults text set to stpfont_normal_bold	N	None	[CT_OS_APP]
TR3050	Exceed Settings – scalable font	Parameter "Default resolution for scalable fonts" set to 96	N	None	[CT_OS_APP]

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3.2.15 SW15, Firewall

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means

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TR3200	The system shall provide a Firewall	Windows Firewall is activated.			N	[RARC_NAV3I.RC81] [RARC_SUITE.RC81] [RARC_NAV3.RC81]	[CT_OS_NET]
TR3210	Support of Firewall – open ports	In the Firewall all ports except the following shall be closed:<table><tr><td>**Name**</td><td>**Private**</td><td>**Public**</td></tr><tr><td>Axeda Desktop Server (UDP)</td><td></td><td>✓</td></tr><tr><td>Axeda Desktop Server (TCP)</td><td></td><td>✓</td></tr><tr><td>Browser Choice</td><td>✓</td><td>✓</td></tr><tr><td>CheckPoint.VPN</td><td>✓</td><td>✓</td></tr><tr><td>Core Networking</td><td>✓</td><td>✓</td></tr><tr><td>Eremoteserver</td><td></td><td>✓</td></tr><tr><td>F5.vpn.client</td><td>✓</td><td>✓</td></tr><tr><td>File and printer Sharing</td><td></td><td>✓</td></tr><tr><td>JuniperNetworsk.junosPulsVpn</td><td>✓</td><td>✓</td></tr><tr><td>LDP Service</td><td>✓</td><td>✓</td></tr><tr><td>Open Text Classic FTP 14</td><td></td><td>✓</td></tr><tr><td>Open Text Exceed 14</td><td>✓</td><td>✓</td></tr><tr><td>Open Text FTP Daemon 14</td><td></td><td>✓</td></tr><tr><td>Open Text InetD 14</td><td></td><td>✓</td></tr><tr><td>Open Text Remote Tools 14</td><td></td><td>✓</td></tr><tr><td>Open Text Xconfig Console 14</td><td></td><td>✓</td></tr><tr><td>Open Text Xfonts Console 14</td><td></td><td>✓</td></tr><tr><td>Open Text Xsession Console 14</td><td></td><td>✓</td></tr><tr><td>Open Text Xstart 14</td><td></td><td>✓</td></tr><tr><td>Play To functionality</td><td>✓</td><td>✓</td></tr><tr><td>Proximity sharing</td><td>(Domain)</td><td></td></tr></table>			N	None	[CT_OS_NET]

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		Remote Assistance	✓				
		SNMP Service	✓	✓			
		SonicWALL.MobileConnect	✓	✓			
		Store		✓			
		UPS Viewer		✓			
		UPS Viewer	✓	✓			
		UPSMAN Tray		✓			
		UPSMAN Tray	✓	✓			
		UPSTCP		✓			
		UPSTCP	✓	✓			
		Wi-Fi Direct Network Discovery		✓			
		Wireless Display	✓	✓			
		Note: The public profile should only be used on a demonstration system. The private network location profile could be applicable in a hospital intranet.					
TR3220	No interruption during normal operation	Firewall notifications shall be disabled.			Y	None	[CT_OS_NET]

140 # 4 Compulsory Requirements

4.1 System reliability

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means

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| TR3300 | Reliability of operating system | System shall run with Passmark BurnInTest for more than 24 hours with 90% duty cycle on

- Processor
- RAM
- 2D Video
- 3D Video
- Network
- Sound
- Hard disk
- Optical drive | N | [DI_NAVIII.SR53020]
[DI_NAV3I.SR53010]
[DI_SUITE.SR503010] | [CT_OS_INST] |

4.2   Internationalization / Localization

ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR3350	Localization – desktop	Support of English (US) Language for user Desktop interface	N	[DI_NAVIII.SR56010] [DI_NAV3I.SR56010] [DI_SUITE.SR506010]	[CT_OS_BASE]
TR3360	Localization – keyboard	Support of English (US) Language for user input keyboard as default. Note: For installation of further input languages refer to [TD]	N	[DI_NAVIII.SR56010] [DI_NAV3I.SR56010] [DI_SUITE.SR506010]	[CT_OS_BASE]
TR3370	Fonts	MS Arial Unicode font shall be installed	N	None	[CT_OS_BASE]

4.3   Installability

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ID	Technical Requirement	Acceptance Criteria	ESS.	Satisfies	Verification Means
TR3400	Installation - Medium	The OS shall be installable from bootable USB device. A change of the boot device is only possible in the boot menu after entering the BIOS password.	N	None	[CT_OS_INST]
TR3410	The OS installation medium offers six options: Installation - option 1	 Clean OS installation including Data and Backup partition. Content of	N	None	[CT_OS_INST]

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		hard disk will be completely deleted before installation.			
TR3420	Installation - option 2	OS installation on Windows partition only. Content of Windows partition on hard disk will be deleted before installation.	N	None	[CT_OS_INST]
TR3430	Installation - option 3	Backup of Windows partition to Windows.wim on Backup partition	N	None	[CT_OS_INST]
TR3440	Installation - option 4	Backup of Data partition to data.wim on Backup partition	N	None	[CT_OS_INST]
TR3450	Installation - option 5	Restore windows partition from Windows.wim on backup partition. Content of Windows partition on hard disk will be deleted before restoration.	N	None	[CT_OS_INST]
TR3460	Installation - option 6	Restore Data partition from data.wim on backup partition. Content of Data partition on hard disk will be deleted before restoration.	N	None	[CT_OS_INST]
TR3480	Platform configuration – options for NavSystem III	For the NavSystem III platform the UPS services have to be deactivated.	N	None	[CT_OS_INST]
TR3490	Platform configuration – options for Nav3i	For the Nav3i platform the UPS services have to be activated. It shall be possible to activate the Axeda Remote Access	N	None	[CT_OS_INST]
TR3500	Support of data backup – DATA	Data backup is possible on USB based drives.	N	None	[CT_OS_INST]
TR3510	Support of data backup – HDD	Full hard disk partition backup shall be possible.	N	None	[CT_OS_INST]
TR3540	Installation Instructions	Installation Instructions shall be provided, which describe the installation procedure, refer to [TD]	N	[DI_NAVIII.SR55010] [DI_NAV3I.SR55010] [DI_SUITE.SR505010]	[CT_OS_INST]
TR3550	Service Guide	A Service Guide shall be provided including following topics: • Hard disk image creation • Recommendations for changes of the system configuration • Recommendations for Windows OS updates • Update of Virus software and definitions update • Firewall availability and settings • Possibility to encrypt partitions and hard disk (Bitlocker) • Permanent deletion of patient data • Installation of additional user input keyboard languages	N	[DI_NAVIII.SR55010] [DI_NAV3I.SR55010] [DI_SUITE.SR514010]	[CT_OS_INST]
TR3560	Licensing	The MS Windows 8.1 license shall be valid (worldwide)	N	None	[CT_OS_INST]
TR3570	Product activation	It shall not be necessary to activate the OS unless new hardware is installed	N	None	[CT_OS_INST]

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4.4   Maintenance

There are no maintenance requirements.

4.5   Regulatory requirements

150   There are no regulatory requirements.

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Review Minute

Review Reference

> **INQP-DLC-005: Design Input Output and Verification / Validation**
>
> **The review team confirms, that the document meets the following requirements:**
>
> - Requirements are traceable to user needs/system requirements, risk controls or other source;
> - Requirements are discrete in nature and not combined.
> - Requirements are complete, unambiguous, non-conflicting, and measurable;
> - All acceptance criteria for requirements are verifiable;

Optional References

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Summary / Result

☐ **Review to be continued**

☐ **Accepted** (no further review)   ☐ **Not accepted** (further review necessary)

    ☐ like it is   ☐ major changes (see list of findings)

    ☐ minor changes (see list of findings)   ☐ new revised version necessary

Follow Up

☐ **Execution and closure of all action items will be approved on document approval.**

☐ **Execution and closure of action items are deferred to the issue tracking system.**   Issue(s): [   ]

☐ **Update of additional tangibles required**

    ☐ update of risk analysis required (add issue)   Issue: [   ]

    ☐ update of other specification required (add issue):   Issue: [   ]

Review Team

Name	Role

DS - Nav3i Platform Family - SPC 3.1 Operating System V2   Rev. D.1   Doc No. 0000039082

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List of Findings	#	Ref. (Ref. No. / part)	Action Item	Resp.
	1			

Signatures for document: Design Specification OS

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Approval Information				
Group	**Approval Role**	**Name**	**Date**	**Vote**
	ARCHITECT	Becher Jochen	Nov 18, 2015 14:51:42 GMT	Approve
	Author	Eisenhauer Richard	Nov 18, 2015 12:24:22 GMT	Approve
	PROJECTLEADER	Schoebel Alexander	Nov 18, 2015 12:14:40 GMT	Approve

Signatures for document: Design Specification OS